

14. (Amended) The method of claim 13, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.8 mIU/m² to about 1.5 mIU/m².

15. (Amended) The method of claim 14, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/m² and wherein said therapeutically effective dose of IL-2 or variant thereof is about 1.0 mIU/m².

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16. (Amended) A method of treating a cancer characterized by overexpression of the HER2 receptor protein in a subject, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and interleukin-2 (IL-2) or variant thereof, wherein said concurrent therapy comprises a first administration of a therapeutically effective dose of IL-2 or variant thereof on day 1 of a treatment period followed by a first administration of a therapeutically effective dose of anti-HER2 antibody or fragment thereof within 6 days of said first administration of said therapeutically effective dose of IL-2 or variant thereof to said subject, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.5 mIU/m² to about 4.0 mIU/m².

17. (Amended) A method of treating a cancer characterized by overexpression of the HER2 receptor protein in a subject, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and interleukin-2 (IL-2) or variant thereof, wherein said concurrent therapy comprises multiple dosing of a therapeutically effective dose of anti-HER2 antibody or fragment thereof and a therapeutically effective dose of IL-2 or variant thereof, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.5 mIU/m² to about 4.0 mIU/m².

18. (Amended) The method of claim 17, wherein said multiple dosing comprises administering to said subject said therapeutically effective dose of IL-2 or variant thereof and said therapeutically effective dose of anti-HER2 antibody or fragment thereof during an introductory cycle, wherein said introductory cycle comprises daily administration of said therapeutically effective dose of IL-2 or variant thereof on day 1 of said introductory cycle through day 20 of said introductory cycle, and a single administration of said therapeutically effective dose of anti-HER2 antibody or fragment thereof on day 7 of said introductory cycle.

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19. (Amended) The method of claim 18, further comprising administering said therapeutically effective dose of IL-2 or variant thereof and said therapeutically effective dose of anti-HER2 antibody or fragment thereof during at least one subsequent cycle, wherein said subsequent cycle comprises daily administration of said therapeutically effective dose of IL-2 or variant thereof on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administration of said therapeutically effective dose of anti-HER2 antibody or fragment thereof on day 1 of said subsequent cycle.

20. (Amended) The method of claim 18, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of IL-2 or variant thereof an intermediate dose of a pharmaceutical composition comprising IL-2 or variant thereof, wherein said intermediate dose comprises about 12.0 mIU/m² IL-2 or variant thereof.

21. (Amended) The method of claim 19, further comprising intermediate-dose IL-2 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of IL-2 or variant thereof an intermediate dose of a pharmaceutical composition comprising IL-2 or variant thereof, wherein said intermediate dose comprises about 12.0 mIU/m² IL-2 or variant thereof.

Please enter the following new claims:

--22. (New) The method of claim 12, wherein said IL-2 or variant thereof is administered subcutaneously.

23. (New) The method of claim 12, wherein said anti-HER2 antibody or fragment thereof comprises at least one human constant region.

24. (New) The method of claim 12, wherein said anti-HER2 antibody is selected from the group consisting of 4D5 and 520C9, or fragment thereof.

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25. (New) The method of claim 24, wherein said anti-HER2 antibody is 4D5 or a humanized, chimeric, or human form thereof.

26. (New) The method of claim 12, wherein said therapeutically effective dose of IL-2 or variant thereof is administered as a pharmaceutical composition selected from the group consisting of a stabilized monomeric IL-2 pharmaceutical composition, a multimeric IL-2 composition, a stabilized lyophilized IL-2 pharmaceutical composition, and a stabilized spray-dried IL-2 pharmaceutical composition.

27. (New) The method of claim 26, wherein said IL-2 is recombinantly produced IL-2 having an amino acid sequence for human IL-2 or variant thereof.

28. (New) The method of claim 27, wherein said variant thereof has an amino acid sequence having at least about 70% sequence identity to the amino acid sequence for said human IL-2.

29. (New) The method of claim 28, wherein said anti-HER2 antibody or fragment thereof comprises at least one human constant region.

30. (New) The method of claim 28, wherein said anti-HER2 antibody is selected from the group consisting of 4D5 and 520C9, or fragment thereof.

31. (New) The method of claim 30, wherein said anti-HER2 antibody is 4D5 or a humanized, chimeric, or human form thereof.

B₃ 32. (New) The method of claim 16, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.6 mIU/m² to about 3.0 mIU/m².

33. (New) The method of claim 32, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.8 mIU/m² to about 1.5 mIU/m².

34. (New) The method of claim 33, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is about 4.0 mg/m² and wherein said therapeutically effective dose of IL-2 or variant thereof is about 1.0 mIU/m².

35. (New) The method of claim 17, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.6 mIU/m² to about 3.0 mIU/m².

36. (New) The method of claim 35, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.8 mIU/m² to about 1.5 mIU/m².

37. (New) The method of claim 36, wherein said therapeutically effective dose of said anti-HER2 antibody or fragment thereof is about 4.0 mg/m² and wherein said therapeutically effective dose of IL-2 or variant thereof is about 1.0 mIU/m².

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38. (New) The method of claim 18, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.6 mIU/m² to about 3.0 mIU/m².

39. (New) The method of claim 38, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.8 mIU/m² to about 1.5 mIU/m².

40. (New) The method of claim 39, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is about 4.0 mg/m² and wherein said therapeutically effective dose of IL-2 or variant thereof is about 1.0 mIU/m².

41. (New) The method of claim 19, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle and on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of IL-2 or variant thereof an intermediate dose of a pharmaceutical composition comprising IL-2 or variant thereof, wherein said intermediate dose comprises about 12.0 mIU/m² IL-2 or variant thereof.

42. (New) A method of treating a cancer characterized by overexpression of the HER2 receptor protein in a subject, said method comprising concurrent therapy with an anti-HER2 antibody or fragment thereof and interleukin-2 (IL-2) or variant thereof, wherein said concurrent therapy comprises daily administration of a therapeutically effective dose of IL-2 or variant thereof on day 1 of an introductory cycle through day 20 of said introductory cycle, and a single administration of a therapeutically effective dose of anti-HER2 antibody or fragment thereof on day 7 of said introductory cycle.

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43. (New) The method of claim 42, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.5 mIU/m² to about 4.0 mIU/m².

44. (New) The method of claim 43, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.6 mIU/m² to about 3.0 mIU/m².

45. (New) The method of claim 44, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of IL-2 or variant thereof is in the range from about 0.8 mIU/m² to about 1.5 mIU/m².

46. (New) The method of claim 45, wherein said therapeutically effective dose of anti-HER2 antibody or fragment thereof is about 4.0 mg/m² and wherein said therapeutically effective dose of IL-2 or variant thereof is about 1.0 mIU/m².

47. (New) The method of claim 42, further comprising administering said therapeutically effective dose of IL-2 or variant thereof and said therapeutically effective dose of